IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, Plaintiffs, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, Defendants.	Civil Action No. 1:19-cv-272-LCB-LPA

AFFIDAVIT OF ALINA NEUBERGER MD, MBA

I, Alina Neuberger, of full age, and pursuant to 28 U.S.C. § 1746, hereby state as follows:

1. I have personal knowledge of the facts set forth in this Affidavit.

2. I am currently a Senior Medical Director in Medical Affairs for CaremarkPCS Health, L.L.C, including CVS Health and its corporate affiliates (collectively "Caremark").

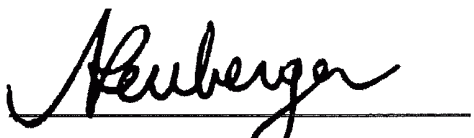
3. I have been employed by Caremark for approximately 5 years.

4. I am familiar with the FDA-approved indications for the testosterone products and hormonal therapies listed in the December 1, 2017 Clinical Plan Management document marked as "**Exhibit A**".

5. None of these products and therapies are FDA approved for the treatment of gender dysphoria.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct.

Executed this __29th__ day of September, 2021 at Chatham, New Jersey.



Alina Neuberger, MD, MBA

Exhibit A

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Clinical Plan Management

The undersigned ("Client") and [CaremarkPCS Health, L.L.C. ("Caremark")] are parties to a Prescription Benefit Services Agreement, as amended from time to time ("Agreement"), pursuant to which Client has retained Caremark to provide certain prescription benefit management and related services with respect to Client's health benefit plan(s). Initially capitalized terms used herein and not expressly defined herein shall have the meanings given to such terms in the Agreement.

Included in the Services that may be provided by Caremark under the Agreement are certain core clinical services and programs and enhanced clinical programs and Services ("Clinical Services"). By executing and returning this Clinical Program Selection Form ("CPM"), Client confirms its election to have Caremark provide Clinical Services under the Agreement in accordance with this CPM.

This CPM is hereby incorporated by reference into the Agreement and shall form part of the Plan Design Document, defined by the Agreement and the prescription drug benefit under Client's applicable health benefit plan(s).

All Clinical Services shall be performed in accordance with the applicable criteria for such Clinical Service ("Criteria"). Unless Client elects below to use custom Criteria for one or more Clinical Services by so indicating on this CPM form, Caremark will provide each Clinical Service in accordance with its standard Criteria as in effect from time to time. Certain clinical services may only be used with standard criteria. The use of standard Criteria is part of the terms and conditions under which Caremark agrees to provide Clinical Services. Subject to the confidentiality provisions of the Agreement, such standard Criteria are proprietary and confidential information of Caremark. Such standard Criteria are not part of Client's health plan or the Plan Design Document. Caremark reserves the right to modify any such standard criteria at any time and from time to time. Modifications of Criteria will not be routinely shared with Client.

To the extent that Client elects to use custom Criteria with respect to one or more Clinical Services, client shall provide Caremark with a copy of such Criteria in writing and Caremark will provide the related Clinical Services in accordance with such written Criteria. In support of custom Criteria derived from plan benefit design or other sources available to Client, Caremark shall work with Client, when requested, in a consultative manner to review clinically-based custom Criteria for consistency with current standards of care. Client shall maintain custom Criteria to ensure alignment with plan benefit design, recommendations from other sources, and standards of care. Clients shall submit custom Criteria to Caremark for review and implementation. Frequency and timing of custom Criteria submission will be at Client's discretion. For clients that wish to implement custom UM edit(s) that have already been developed for another line of business, please indicate this within the following sections of this form.

- Special Instructions/Notes section
- Client Request-Custom section at the end of each UM edit type area

Within these sections, please indicate the following: [ENTER SPECIFIC XYZ Plan List NAME] for each of the custom edits to be implemented.

Client may elect to discontinue provision of any Clinical Service through written notice to Caremark.

By signing below, Client hereby accepts and adopts as its own the Criteria, as administered by Caremark. In the event Client elects to implement its own criteria, Client acknowledges Caremark will not evaluate and update such custom criteria for safety or efficacy and Client shall be responsible to notify Caremark of any changes to such criteria.

I have reviewed the attached documentation and conclude all information to be correct. (All signatures below are required)

Client (Company) Name: North Carolina State Health Plan	Version
Client Signature:	Date: 12/06/17
Signatory Name: Client Does Not Sign CPM Form – Refer to Approval Email	
Signatory Title:	

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RxClaim Only

Client hierarchy for utilization management appropriateness and SGM programs
Carrier: 0274 and 0275
Carrier – Account:
Carrier – Account – Group:
Do the selected clinical programs apply to all members or specific groups of members? ☒ All members ☐ Specific groups (specified below)
Please specify details here:

***Note: Not all dosage forms will accumulate across the entire class.**

RxClaim Only

Client hierarchy for Formulary Alternatives program exclusion
Formulary Alternatives provides alternatives via preferred product fields of claim response sent to pharmacies, and Real Time Benefits EHR transactions, shared with prescribers. Opting the client out will exclude the communication of alternatives through both of these communication channels.
Opt out client ☐
List Carrier – Account – Group for opt out (available at any level of CAG):
Please specify details here:

Caremark Internal Only – UM and SGM and PDPD DO NOT DELETE THIS TABLE! This is required information.

Additional Client Details and Caremark contacts	
Client FAF ID: Client Rebate ID:	
Client Type: ☒ Employer ☐ Stand Alone Specialty Client ☐ Health Plan ☐ TPA	
-To ensure notifications from the Prior Authorization and Appeals department do not violate HIPAA or other privacy regulations, it is important to determine if the client or vendor is sending the member's Social Security Number (SSN) on the eligibility file. The standard process when generating notifications is to retrieve the member identification number from the Cross Walk ID on the eligibility file. If the Cross Walk ID contains the SSN, the Prior Authorization and Appeals department will need to ensure that the Member ID is on the eligibility file is being used for notifications. If the Member ID or Crosswalk ID field contains a SSN, the other field must contain a member Identification number to generate on notifications. Please ask the account manager or Eligibility Administrator the following questions. Is the client or vendor sending the member's SSN on the eligibility file: Yes ☒ No ☐ If yes, which field will the SSN be stored? Crosswalk ID ☒, Member ID ☐	
Standard Formulary Status: ☐ Opt-in with NDC Block ☒ Opt-in with PA Option ☐ Opt-out As of 10/15/2015, Opt-in with NDC Block will require that clients provide an exception pathway for members so please note that the option to select that offering has been removed from the CPM form.	
Client Company Name: North Carolina State Health Plan (Please list client name as it should appear on PA and Appeal letters and fax forms.)	
Client Address:3200 Atlantic Avenue City: Raleigh State: NC Zip: 27604	
Total # of Plan Members* : 550,000	
Clinical Advisor: Renee Jarnigan/Stephanie Morrison	SAE: Brian Hemreck
Account Manager: Bree Nelson/Karyn Donohoe/Jim Loveday	Account Executive:
Specialty-CRU:	Implementation Manager:
Benefits Relationship Manager (BRM)**: Drew Anderson	
Benefits Consultation Center (BCC)**: ☒ BCC RxClaim ☐ BCC Recap	
Specialty Account Executive:	CRU Implementation Specialist:
Customer Care Provided by: ☒ Caremark ☐ Client	Customer Care Phone Number:
* Please provide Total # of Plan Members if known - this is used to project PA call volume	

**** Clinical Advisor must either list a BRM contact or select a BCC mailbox before routing this CPM form**

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For NON-Grandfathered Plans (80/20 and CDHP):

Applicable Laws – UM and SGM and PDPD DO NOT DELETE THIS TABLE! This is required information for the PA & Appeals department.

1. What line of business is your client?

☒ Commercial, HP Commercial, Self-Insured Employer Group, Third Party Administrator (TPA) or Coalitions ➡ Go to #2
☐ Exchange, Small Business Health Option Program (SHOP), or Fully-Insured, Individual, or Small Group Plans (Off-Exchange) ➡ Go to #6
☐ Managed Medicaid, HP Dual Demo ➡ Go to #7
☐ Medicare, EGWP ➡ No further information is needed

2. Is your client grandfathered or a retiree-only plan?

☐ Yes ➡ Go to #3
☒ No ➡ Go to #4

3. If grandfathered or retiree-only, what laws are they subject to?

☐ ERISA ONLY (e.g. Self-Insured Employer Plans, ASO [Administrative Services Only], Retiree-Only Self-Insured Employer Plans, Self-Insured Union Plans) ➡ Done
☐ State Law ONLY (e.g. Fully-Insured Health Plan, Certain Self-Insured Government Plans) ➡ Go to #5
☐ ERISA & State Law (e.g. Fully-Insured Employer Plans, Retiree-Only Fully-Insured Employer Plans) ➡ Go to #5
☐ Other (e.g. Self-Insured Government Plans and Self-Insured Church Plans) ➡ Specify what requirements your client is subject to, including any contractual provisions relating to utilization review, prior authorization, appeals, external review: _____ ➡ Done

4. If not grandfathered, what laws are they subject to?

☐ ACA requirements applicable to non-grandfathered plans & ERISA (e.g. Self- Insured Employer Plan, ASO [Administrative Services Only], Self-Insured Union Plan) ➡ Done
☐ ACA requirements applicable to non-grandfathered plans & State law (e.g. Fully- Insured Health Plan [including Fully-Insured Government and Church Plans] Certain Self-Insured Government Plans, Exchange Plans, Individual Off- Exchange Plans and Small Group Off-Exchange Plans) ➡ Go to #5
☐ ACA requirements applicable to non-grandfathered plans, ERISA, & State Law (e.g. Fully-Insured Employer Plans, Fully-Insured Union Plans) ➡ Go to #5
☐ ACA requirements applicable to non-grandfathered plans ONLY (e.g. Self- Insured Government and Self-Insured Church Plan). ➡ Done
☒ ACA requirements applicable to non-grandfathered plans & Other (e.g. Self- Insured Government and Self-Insured Church Plan). ➡ Specify what laws your client is subject to, including any contractual provisions relating to utilization review, prior authorization, appeals, external review: _____North Carolina_____ ➡ Done

5. Is your client a fully-insured health plan that operates in multiple states and subject to State of Precedence (SOP) requirements?

☐ Yes: Contract state. Please type state abbreviation(s): _____ ➡ Go To #7
☒ No ➡ Go To #7

** If Question #5 is answered "YES", then contact with Eligibility or the account team that handles eligibility will need to be notified as additional fields will need to be added to the members group profile information. This information will need to be obtained from the client and loaded into Rxclaim.**

6. Is your client a multi-state plan regulated by Office of Personnel Management (OPM)?

☐ Yes ➡ Go to #7
☒ No ➡ Go to #7

7. What state law does your client follow?

☒ Please type state abbreviation: _____NC_____ ➡ Go to #8

8. Within the state law that was indicated above, does your client follow?

☒ State Insurance Laws (e.g. Insure or PPO) ➡ Done
☐ Managed Health Care Laws (e.g. HMO) ➡ Done

☐ Managed Medicaid Requirements (e.g. State model contracts) ➡ Done
☐ Medicare Medicaid Plan/Dual demonstrations Plans (e.g. Three way contract between CMS, state, and plan) ➡ Done
Other ➡ Done. If other, please specify what laws your client is subject to: _____

For Grandfathered Plans (70/30 and 70/30 MA):

Applicable Laws – UM and SGM and PDPD DO NOT DELETE THIS TABLE! This is required information for the PA & Appeals department.

1. What line of business is your client?
☒ Commercial, HP Commercial, Self-Insured Employer Group, Third Party Administrator (TPA) or Coalitions ➡ Go to #2
☐ Exchange, Small Business Health Option Program (SHOP), or Fully-Insured, Individual, or Small Group Plans (Off-Exchange) ➡ Go to #6
☐ Managed Medicaid, HP Dual Demo ➡ Go to #7
☐ Medicare, EGWP ➡ No further information is needed

2. Is your client grandfathered or a retiree-only plan?
☒ Yes ➡ Go to #3
☐ No ➡ Go to #4

3. If grandfathered or retiree-only, what laws are they subject to?
☐ ERISA ONLY (e.g. Self-Insured Employer Plans, ASO [Administrative Services Only], Retiree-Only Self-Insured Employer Plans, Self-Insured Union Plans) ➡ Done
☐ State Law ONLY (e.g. Fully-Insured Health Plan, Certain Self-Insured Government Plans) ➡ Go to #5
☐ ERISA & State Law (e.g. Fully-Insured Employer Plans, Retiree-Only Fully-Insured Employer Plans) ➡ Go to #5
☒ Other (e.g. Self-Insured Government Plans and Self-Insured Church Plans) ➡ Specify what requirements your client is subject to, including any contractual provisions relating to utilization review, prior authorization, appeals, external review: ___North Carolina_____ ➡ Done

4. If not grandfathered, what laws are they subject to?
☐ ACA requirements applicable to non-grandfathered plans & ERISA (e.g. Self- Insured Employer Plan, ASO [Administrative Services Only], Self-Insured Union Plan) ➡ Done
☐ ACA requirements applicable to non-grandfathered plans & State law (e.g. Fully- Insured Health Plan [including Fully-Insured Government and Church Plans] Certain Self-Insured Government Plans, Exchange Plans, Individual Off- Exchange Plans and Small Group Off-Exchange Plans) ➡ Go to #5
☐ ACA requirements applicable to non-grandfathered plans, ERISA, & State Law (e.g. Fully-Insured Employer Plans, Fully-Insured Union Plans) ➡ Go to #5
☐ ACA requirements applicable to non-grandfathered plans ONLY (e.g. Self- Insured Government and Self-Insured Church Plan). ➡ Done
☒ ACA requirements applicable to non-grandfathered plans & Other (e.g. Self- Insured Government and Self-Insured Church Plan). ➡ Specify what laws your client is subject to, including any contractual provisions relating to utilization review, prior authorization, appeals, external review: _____North Carolina_____ ➡ Done

5. Is your client a fully-insured health plan that operates in multiple states and subject to State of Precedence (SOP) requirements?
☐ Yes: Contract state. Please type state abbreviation(s): _____ ➡ Go To #7
☒ No ➡ Go To #7

** If Question #5 is answered "YES", then contact with Eligibility or the account team that handles eligibility will need to be notified as additional fields will need to be added to the members group profile information. This information will need to be obtained from the client and loaded into Rxclaim.**

6. Is your client a multi-state plan regulated by Office of Personnel Management (OPM)?
☐ Yes ➡ Go to #7
☒ No ➡ Go to #7

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7. What state law does your client follow?

☒ Please type state abbreviation: _____NC_____ ➡ Go to #8

8. Within the state law that was indicated above, does your client follow?

☒ State Insurance Laws (e.g. Insure or PPO) ➡ Done
☐ Managed Health Care Laws (e.g. HMO) ➡ Done
☐ Managed Medicaid Requirements (e.g. State model contracts) ➡ Done
☐ Medicare Medicaid Plan/Dual demonstrations Plans (e.g. Three way contract between CMS, state, and plan) ➡ Done
Other ➡ Done. If other, please specify what laws your client is subject to: _____

For clients that wish to implement custom UM edit(s) that have already been developed for another line of business, please indicate this within the following sections of this form.

- **Special Instructions/Notes section below.**
- **Client Requested-Custom section at the end of each UM edit type area**

Within these sections, please indicate the following: [ENTER SPECIFIC XYZ Plan List NAME] for each of the custom edits to be implemented.

Special Instructions/Notes

The purpose of this CPM is to (1) remove PA for testosterone products for transgender care, (2) add PA to testosterone products for non-transgender care, (3) exclude transgender care diagnoses for Hormonal Therapies SGM (Eligard, Luron Depot, Trelstar Dep/LA/Mix, Vantas, Zoladex, Supprelin LA), (4) change NC SHP custom SGM criteria for Lupron/leuprolide to exclude transgender care/gender dysphoria effective 1/1/18.

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Prior Authorization Non-Specialty (Standard, Featured) *continued*

Category	Action	PA Renewal Notification	Criteria
Testosterone Products – Transgender Care Approvable **Select either 12-month or 36-month approval duration option.** **Note: Oral testosterone agents are not approvable for transgender care. If PA on oral testosterone agents is desired, select either the 12-month or 36-month oral testosterone PA under the "Testosterone Products – No Coverage for Transgender Care" section.**			
36-month approval duration			
Testosterone Products (Brand and Generic)	☐Add ☒Delete ☐Change	☐Accept ☐Decline	☒Testosterone Products TGC 1210-A (36-month DoA)
	Target Drugs: Enanthate injection, Cypionate injection, topical gel, topical cream, topical ointment, topical solution, transdermal patch, nasal gel, mucoadhesive buccal system, propionate implant pellets		
Testosterone Products – No Coverage for Transgender Care **Select either 12-month or 36-month approval duration option.**			
36-month approval duration			
Testosterone Products (Brand and Generic)	☒Add ☐Delete ☐Change	☐Accept ☐Decline	☒Testosterone Products Non-TGC 1215-A (36-month DoA)
	Target Drugs: Enanthate injection, Cypionate injection, topical gel, topical cream, topical ointment, topical solution, transdermal patch, nasal gel, mucoadhesive buccal system, propionate implant pellets		

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SGM Program Therapies (Standard)

Therapy	Drug	Total # of Existing patients	Add	Delete	Drug	Total # of Existing patients	Add	Delete
Hormonal Therapies	Select All		☐	☐	Previous PA with CMK or other vendor		☐Yes	☐No
	Aveed		☐	☐	Trelstar Dep/LA/Mix		☐	☐
	Eligard		☐	☐	Vantas		☐	☐
	Firmagon		☐	☐	Zoladex		☐	☐
	Natpara		☐	☐	Supprelin LA		☐	☐
	Leuprolide acetate		☐	☐	Lupaneta		☐	☐
	Lupron Depot		☐	☐	TRIPTODUR		☐	☐
	☒ **Exclude these products for transgender care diagnoses: Eligard (Eff 07/03/2016), Lupron Depot, Trelstar Dep/LA/Mix (Eff 07/03/2016) , Vantas (Eff 07/03/2016), Zoladex (Eff 07/03/2016), Supprelin LA (Eff 07/03/2016).**							
	Comments:							

SGM Program Therapies (Client requested - Custom)

Lupron Depot Endometriosis-Fibroids NCSHP SGN 12-2016	**Action:** ☐ Add ☐ Delete ☒ Change
	Drugs In Class: Lupron Depot/Leuprolide
	Criteria: Custom SGM program for NCSHP – Update criteria to EXCLUDE coverage of TGC/gender dysphoria diagnoses.